UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 1:18-OP-45090 *The County of Cuyahoga v. Purdue Pharma L.P., et al.* Case No. 17-OP-45004	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MANUFACTURER DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT THAT PLAINTIFFS' STATE-LAW CLAIMS ARE PREEMPTED AND THEIR FEDERAL CLAIMS ARE PRECLUDED

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INTRODUCTION

The parties appear to agree: federal law allows the Manufacturers to market consistent with their medications' FDA-approved indications and labeling, and a claim that would impose liability for that lawful conduct is preempted (state-law claims) or precluded (RICO claims). One of the issues presented by this motion is whether Plaintiffs are challenging such protected conduct. Plaintiffs say they are not, but the evidentiary record makes clear that they are. In fact, Plaintiffs' entire "causation" model is built on an assumption that each and every interaction between a Manufacturer's sales representative and a physician was unlawful. To avoid preemption and preclusion, Plaintiffs would need to focus on interactions in which sales representatives made false statements inconsistent with a medication's labeling. But Plaintiffs have made no effort to do so, and thus have swept within their claims conduct that is protected from legal challenge.

In a desperate attempt to avoid preemption and preclusion, Plaintiffs obfuscate and dissemble. For example, Plaintiffs concede that federal law preempts challenges to the FDA-approved labeling of the Manufacturers' opioid medications, but claim, incredibly, that Plaintiffs challenge only marketing and promotional activities, not labeling. But as a matter of law, labeling broadly encompasses marketing and promotional activities. *See, e.g.*, *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013); *see also* 21 U.S.C. § 321(m).

Plaintiffs also argue that the FDA did not *clearly* reject the additional warnings Plaintiffs claim are needed and that, even if it did, that rejection occurred years ago and does not establish what the FDA would decide today. Opp'n at 14. But Plaintiffs misstate the record. The FDA rejected Plaintiffs' arguments and reaffirmed that the Manufacturers could market their medications for the long-term treatment of chronic, non-cancer pain, without additional dose and

duration limits and warnings. *See* Ex. 12.[1] The FDA reiterated those same positions as recently as May 2019, reaffirming the delicate public health balance that the FDA is uniquely equipped to strike. *See* Ex. 1. The FDA's findings remain "clear evidence" that it would have rejected the labeling changes Plaintiffs now seek—all that is required for preemption to apply. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019); *Wyeth v. Levine*, 555 U.S. 555 (2009). Moreover, Plaintiffs' theory of the case assumes that *every instance* of marketing by the Manufacturers was unlawful. Thus, the Court need only find that the FDA rejected *one* of the labeling changes that Plaintiffs' claims would require in order for Plaintiffs' *entire* assumption to be invalid and for *all* of their marketing claims to be preempted or precluded.

Plaintiffs also attempt to avoid the preemptive effect of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), with the suggestion that their claims do not require showing that the Manufacturers defrauded the DEA into increasing quotas for permissible sales. But their complaints—and the expert opinions offered in support of their claims—show otherwise. *See, e.g.*, Third Am. Compl. ("Summit TAC") ¶¶ 526, 761, 961, ECF No. 1466 (alleging that the Manufacturers "fraudulently increase[d] the quotas that governed the manufacture and distribution of their prescription opioids"); Ex. 16 (Expert Report of James Rafalski) ("Rafalski Report") at 46 (identifying alleged "failures to comply with the requirements of the Controlled Substances Act" that allegedly "led to the excess quantity of opiate pills flooding the illicit market"); Ex. 14 (Pls' Dec. 28, 2018 Suppl. Objs. & Resp. to Mfr Defs.' Interrog. Nos. 28/29) ¶ 30 (emphasis added) (Manufacturers "fraudulently increas[ed] the quotas set by the DEA that would *allow them* to collectively benefit from a greater pool of prescription opioids to manufacture and distribute"

[1] All exhibits referenced herein are exhibits to the Declaration of Jonathan L. Stern in Support of Manufacturer Defendants' Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded.

(emphasis added)); *see also* Mem. In Supp. of Pls' Mot. for Summ. J. of Defs' Duties Under the Controlled Substances Act at 4 (Dkt. 1887-1) (focusing on supposed reporting requirements under the CSA). Indeed, Plaintiffs' only theory is that the Manufacturers were able to flood the market because they deceived the DEA into increasing sales quotas, and the Court has already found that fraud on the DEA is a part of Plaintiffs' theory of but-for causation.

For these reasons, Plaintiffs' marketing and fraud-on-the-DEA claims are either preempted (state-law claims) or precluded (federal-law claims).

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE PREEMPTED OR PRECLUDED BECAUSE THEY SEEK TO REQUIRE WARNINGS THAT THE FDA PREVIOUSLY REJECTED

As explained in the opening memorandum (ECF No. 1926-1 at 4-14), federal law preempts or precludes Plaintiffs' claims because they seek to hold the Manufacturers liable for failing to add certain warnings to their marketing materials for opioid medications despite "clear evidence" that the FDA would have rejected those warnings. *See Merck*, 139 S. Ct. at 1678 (2019). Plaintiffs' opposition does nothing to avoid this result.

A. Plaintiffs' Claims Improperly Challenge The FDA-Approved Labeling For Opioid Medications

To avoid preemption, Plaintiffs once again rely chiefly on a false distinction between labeling and marketing, claiming that they "do not challenge the FDA-approved labeling of any of Manufacturers' products, but rather their false and misleading promotion of those drugs." Opp'n at 10. But as both the Sixth Circuit and this Court have recognized, the statutory term "labeling" encompasses "representations made in marketing materials." *Muscogee* R. & R. at 30, ECF No. 1499, *adopted by* Op. & Order at 2, ECF No. 1680; *see also Strayhorn*, 737 F.3d at 394 (noting that "advertising and promotional materials are considered labeling"); 21 U.S.C. § 321(m) ("labeling" includes "written, printed, or graphic matter" that "accompan[ies]" a drug); 21 C.F.R.

§ 202.1(l)(2) ("labeling" includes, among other things, "detailing pieces"). Once the FDA approves a medication as safe and effective for a particular indication and requires the "labeling" to state that fact, the manufacturer cannot include contrary representations in its marketing materials without running afoul of the FDA's regulatory commands and running the risk that the FDA will declare its product misbranded.

Yet that is precisely what Plaintiffs' claims would require here. Plaintiffs' claims depend on their allegations that the Manufacturers made a series of misrepresentations and omissions in marketing materials for their opioid medications—each of which must have been fraudulent for their causation and damages model to hold. *See, e.g.*, Summit TAC ¶ 172; *see also* Mem. at 4-14, ECF No. 1926-1. Plaintiffs' own evidence confirms that they are challenging every instance of the Manufacturers' opioid marketing, including marketing of the medications for the FDA-approved use of long-term treatment of chronic, non-cancer pain. *See, e.g.*, Ex. 3 (Expert Report of Anna Lembke, M.D. ("Lembke Report")) at 21-63 (asserting that drug manufacturers "overstate[d] [the] benefits of long-term use for chronic pain" and understated its risks); Mem. at 5-8; *see also, e.g.*, Pls' Consol. Mem. in Opp'n To Defs' Motions for Summ. J. on Proof of Causation (Corrected), ECF No. 2204, at 7 ("Defendants also inaccurately promoted opioids as safe to use at increasing dose levels."); *id.* at 11 ("There is also evidence that each Manufacturer Defendant's marketing and promotion overstated the benefits of opioids for long-term use without scientific support for such statements."). Indeed, Plaintiffs assert "that *all* of Defendants' promotional activity was fraudulent" and that "*every* opioid prescription written" after certain defendants began marketing opioids for chronic, non-cancer pain in 1995 "was infected by fraud." Rosenthal Opp'n Br. at 5 (first emphasis added). They further claim "that this fraud affected not only whether to prescribe an opioid, but also at what dose, for what duration, with what warnings

to the patient." *Id.*

Plaintiffs do not dispute this point. Rather, they dispute that the evidence they developed is even relevant to the inquiry and urge the Court to look only to their pleadings to determine the content of their claims. Opp'n at 12 & n.5. On summary judgment, however, the inquiry is whether "*the evidence* presents a sufficient disagreement to require submission to a jury." *Doe v. City of Memphis*, 928 F.3d 481, 486 (6th Cir. 2019) (emphasis added) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251–52 (1986)). Here, that evidence indicates precisely what the Manufacturers have argued all along—that Plaintiffs seek to hold them liable for marketing opioid medications for an FDA-approved use, even though their own experts have confirmed that the Manufacturers engaged in marketing activities that were entirely lawful and appropriate. *See* Kessler Dep. Tr. (ECF No. 1979-9) at 758:10–760:8 (confirming that one Manufacturer's conveyance of corrective information to prescribers was appropriate); Perri Dep. Tr. (ECF No. 1983-5) at 581:10–596:4 (confirming that certain marketing materials contain statements taken directly from the opioid product's approval letter or FDA-approved package insert); Schumacher Dep. Tr. (ECF No. 1984-11) at 109:8–17 (failing to recall a single instance in which false or misleading information was received). Plaintiffs cite no authority (nor could they) suggesting the Court should ignore this evidence on summary judgment.

Plaintiffs also argue that there can be no preemption "because federal law did not *require* Manufacturers to promote their products," so the Manufacturers could have complied with both state and federal law by not promoting their products. Opp'n 10-11. But this argument is contrary to settled Supreme Court and Sixth Circuit precedent. In *Wyeth* and *Merck*, federal law did not *require* the manufacturer to sell its medications, so in theory the manufacturer could have complied with both state and federal law simply by taking its product off the market. But the Supreme Court

declined to construe preemption doctrine so narrowly. *See, e.g.*, *Merck*, 139 S. Ct. at 1681 (Thomas, J., concurring) (explaining that preemption should apply where "federal law gives an individual the right to engage in certain behavior that state law prohibits, . . . notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior" (citation omitted)); *see also Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013) ("[A]n actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."); *In re Darvocet, Darvon, and Propoxyphene Prods. Liability Litig.*, 756 F.3d 917, 925 (6th Cir. 2014) (noting that the "*Bartlett* court rejected the 'stop selling' theory, namely that a generic manufacturer could have avoided the conflict between state and federal law by refraining from selling the drug").

Instead, the Supreme Court held that, when the FDA is "fully informed" of the "justifications for [a] warning required by state law" and nonetheless provides "clear evidence" that it "would not approve a change to the drug's label to include that warning," preemption applies. *Merck*, 139 S. Ct. at 1678. Plaintiffs' suggestion that the Manufacturers could have complied with both their state- and federal-law obligations simply by *not marketing* their opioid medications directly contradicts Supreme Court and Sixth Circuit precedent.

B. The Manufacturers Have Presented Clear Evidence That The FDA Would Have Rejected The Labeling Changes Plaintiffs' Claims Would Require

Plaintiffs next argue that the Manufacturers have provided insufficient evidence that the FDA would have rejected the warnings that Plaintiffs say the Manufacturers should have given. Plaintiffs first seek to undermine the significance of the FDA's response to the PROP petition, arguing that the response did not specifically address the "fraudulent representations upon which Plaintiffs' claims are based." Opp'n at 13. But this is false: the FDA's response *did* address, for example, the alleged misrepresentation that "[o]pioid doses can be increased without limit or

greater risks." Summit TAC ¶ 172(e); *see* Ex. 12 at 11-17 (specifically declining to "specify or recommend a maximum daily dose or duration of use for any opioid" and explaining that such limits were "not supportable" by the relevant scientific literature).[2] The FDA's response addressed at length the safety of opioid medications for long-term treatment of chronic, non-cancer pain. *Id.* at 7-10. The FDA's conclusion that the medications were safe and effective for that use is inconsistent with the additional warnings that Plaintiffs claim Ohio law required.

And even if the Court were to find that the FDA rejected some but not all of the labeling changes that Plaintiffs claim were required, that would still be sufficient to find that *all* of Plaintiffs' claims are preempted or precluded. That is because Plaintiffs' case assumes that *every instance* of marketing by the Manufacturers was unlawful. *See*, *e.g.*, Pls' Consolidated Memo. in Opp'n To Defs' Motions for Summ. J. on Proof of Causation (ECF No. 2204) at 3-4 ("Defendants used multiple promotional and marketing approaches—all of which were unlawful and fraudulent . . . ."); *id.* at 51 ("The Court should reject Defendants' attack on Plaintiffs' aggregate proof model based on Dr. Rosenthal's treatment of all prescription opioid detailing as unlawful . . . . This is exactly what Plaintiffs asked Dr. Rosenthal to do."); *see also*, *e.g.*, Pls' Mem. in Opp'n To Defs' Mot. to Exclude "Marketing Causation" Opinions of Drs. Schumacher, Lembke and Keyes (ECF No. 2166) at 6-7, 10, 15-16; Pls' Mem. in Opp'n To Defs' Mot. to Exclude the Test. of David Kessler, MD, and Matthew Perri (ECF No. 2195) at 18. Thus, if the FDA found that even one alleged misrepresentation was in fact lawful and need not be changed, that would destroy Plaintiffs' assumption that all marketing was unlawful.

Plaintiffs note that the FDA required some labeling changes in response to the PROP

[2] Should the Court conclude that the FDA considered some but not all of the misrepresentations that Plaintiffs allege and also decline to find that all of Plaintiffs' claims are preempted or precluded given Plaintiffs' assumption that all marketing was unlawful and their aggregate theory of causation, the Court should at minimum hold that Plaintiffs' claims are preempted as to those misrepresentations.

petition. Pls.' Opp'n at 13. The FDA did make certain changes to the labels for extended-release and long-acting opioid medications that were intended to "better enable[] prescribers to make decisions based on a patient's individual needs." Ex. 12 at 8. But critically, the FDA rejected the maximum-dose and duration warnings that the PROP petition urged and that Plaintiffs again demand here. Nor did the FDA ratify PROP's assertion that opioid medications are unsafe for the long-term treatment of chronic, non-cancer pain. In short, Plaintiffs impermissibly seek to hold Defendants liable under Ohio law for failing to provide warnings that the FDA, faced with the same scientific issues, declined to impose.

Plaintiffs further argue that the age of the PROP petition undermines its value. For this proposition, Plaintiffs point to a Seventh Circuit case which found the rejection of a citizen petition "not . . . very compelling for either side," where the FDA rejected the petition "several years" before the plaintiffs' daughter committed suicide (which she did shortly after taking an antidepressant manufactured by the defendants). *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 395 (7th Cir. 2010). But the *Mason* court believed that the "temporal gap" was important in the context of that case because there was no indication that the agency still held its previously expressed beliefs at the time of the plaintiff's injury. *Id.* (noting that "the analysis of prescription drugs . . . constantly evolves as new data emerges").

Here, by contrast, the FDA holds the same position in 2019 as it did in 2014 when it rejected the PROP petition's proposed labeling changes. Specifically, in a May 2019 memorandum, the FDA wrote that opioid medications continue to "provide clinically significant analgesic benefit, including for pain for which other analgesics are inadequate." *See* Ex. 1 (May 2019 FDA Mem.) at 9. Moreover, the memo notes that an FDA task force met in May 2019 and, like the agency did in 2013, "*did not recommend* any absolute limits on the individual dose or total daily dose of opioid

analgesics." *Id.* at 12 (emphasis added). Thus, far from being "irrelevant" (Opp'n at 15), the May 2019 memorandum undermines Plaintiffs' attempt to discredit the FDA's rejection of a citizen petition by demonstrating that the FDA still holds the same views it held in 2014 when it largely denied the PROP petition. *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1103 (10th Cir. 2017) (distinguishing *Mason* on the ground that the citizen petitions at issue there "had been rejected before the plaintiff's injury"); *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010) (finding "clear evidence" of preemption based on "the agency's refusal to require a [warning] on the label" after the plaintiff's injury occurred).

Plaintiffs also suggest that the North Dakota court that recently dismissed similar claims against Purdue on preemption grounds might reach a different conclusion were it asked to reconsider it today. Opp'n at 16 n.7. But nine days *before* Plaintiffs filed their opposition, the North Dakota court rejected the State of North Dakota's motion for relief from judgment. *See* Order Denying Pl's. Rule 60(b) Mot. For Relief from Judgment, *N. Dakota v. Purdue Pharma L.P.*, No. 08-2018-CV-01300, 2019 WL 3776653 (N.D. Dist. Ct. July 22, 2019). The North Dakota court explained that the Supreme Court's recent decision in *Merck* did not change the conclusion that federal law preempts the State's claims. *See id.* Thus, rather than back away from its prior preemption finding, the North Dakota court reaffirmed it in light of *Merck*.

This Court should reach the same result and find that federal law preempts Plaintiffs' claims seeking to hold the Manufacturers liable for marketing opioid medications for the treatment of chronic, non-cancer pain and for failing to recommend dose and duration limitations. For the same reasons, the Court should find that Plaintiffs' federal-law claims are precluded.[3] *See*, *e.g.*,

[3] Plaintiffs notably do not challenge Manufacturers' recitation of preclusion doctrine, and thus that issue is not in dispute. *See* Opp'n at 17.

POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 111-12 (2014) (noting that preemption "principles are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject").

II. PLAINTIFFS' CLAIMS ARE PREEMPTED OR PRECLUDED BECAUSE THEY ARE PREMISED UPON FRAUD ON THE DEA.

Plaintiffs do not dispute that, if their state-law claims in fact depend upon a fraud on the DEA, those claims are preempted under *Buckman*, 531 U.S. 341. *See* Mem. at 3-4, 14-20.[4] To avoid that fate, Plaintiffs argue that their claims do *not* turn on proving that the Manufacturers defrauded the DEA into increasing permissible quotes for the sale of prescription opioid medications. *See*, *e.g.*, Opp'n at 17 ("Plaintiffs' claims against Manufacturers do not depend upon the DEA's decision to increase quotas for opioid medications . . . . The increased DEA quotas . . . do not in and of themselves form the basis of Plaintiffs' claims."). Plaintiffs now want the Court to believe that their claims rest *only* "on the Manufacturers' fraudulent and misleading promotion directed toward healthcare providers, which drove the massive increase in prescriptions . . . ." *Id.* But Plaintiffs' post-hoc characterization of their claims has no basis in the record and is belied by the RICO "Supply-Chain Enterprise" theory that they pursue. Plaintiffs cannot be permitted to escape the record they chose to create in this case.

Plaintiffs chose to allege, for example, that it would have been "impossible" for the Manufacturers to "achieve their ever-increasing sales ambitions" had they not "fraudulently increase[d] the quotas that governed the manufacture and distribution of their prescription opioids." Summit TAC ¶ 526; Cuyahoga TAC ¶ 510; *see also* Summit TAC ¶¶ 548–553;

[4] As the Non-RICO Small Distributors' Defendants have explained, *Wyeth* and *Merck* do not limit *Buckman* preemption. *See* Non-Rico Small Distributors' Aug. 16, 2019 Reply Memorandum In Support Of Their Motion For Partial Summary Judgment On Plaintiffs' "Failure To Report" And "Fraud On The DEA" Claims at Section II. Nor does 21 U.S.C. § 903 act as a "savings clause" that permits Plaintiffs' tort claims to proceed. *Id.* at Section III.

Cuyahoga TAC ¶¶ 531–536. Plaintiffs further chose to declare that the Manufacturers "fraudulently increas[ed] the quotas set by the DEA that would *allow them* to collectively benefit from a greater pool of prescription opioids to manufacture and distribute." Ex. 14 (Pls' Dec. 28, 2018 Suppl. Objs. & Resp. to Mfr Defs.' Interrog. Nos. 28/29) ¶ 30 (emphasis added); *see also id.* ¶ 28 (alleging the Manufacturers "achieved blockbuster profits through higher opioid sales *by orchestrating the unimpeded flow of opioids*" (emphasis added)). Indeed, the Court already determined that Plaintiffs' claims depend on a theory of fraud on the DEA—a finding that should end any debate here. The Court found that Plaintiffs claim injury not just from the "allegedly deceptive marketing scheme," but also from "the systemic undermining of quotas and institutional controls" established by the DEA. *Summit County* R. & R., ECF No. 1025 at 26. As the Court found, Plaintiffs' theory is that, without a fraud on the DEA, "the number of opioids would not have tripled or quadrupled thereby directly giving rise to the opioid epidemic—the costs of which have resulted in Plaintiffs' alleged injuries." *Id.*

Plaintiffs' expert similarly states that Plaintiffs' claims are premised on "failures to comply with the requirements of the Controlled Substances Act" that "led to the excess quantity of opiate pills flooding the illicit market." Ex. 16 (Rafalski Report) at 46. Plaintiffs' experts noticeably do not state that the alleged surplus of prescription opioid medications in the market—the very heart of this case—occurred independently from the alleged fraud on the DEA.[5] With discovery now completed, Plaintiffs have presented no evidence—other than a fraud-on-the-DEA theory—to support their claims that the Manufacturers flooded the market with excess opioid medications.[6]

[5] For example, neither Plaintiffs nor their experts seek to prove that the Manufacturers sold quantities of prescription opioid medications that were *greater than* the quotas established by the DEA.

[6] Plaintiffs' summary judgment briefing continues to argue that the Manufacturers were obligated to report to the DEA and failed to do so. *See*, *e.g.*, Mem. in Supp. of Pls' Mot. for Summ. J. of Defs' Duties Under the Controlled Substances Act (ECF No. 1887-1) at 3-4; Pls' Consolidated Memo. in Opp'n To Defs' Motions for Summ. J. on Proof of Causation (Corrected) (ECF No. 2204) at 23, 24.

Plaintiffs' claims thus fall squarely under the preemptive rubric of *Buckman*.[7] *See*, *e.g.*, *Buckman*, 531 U.S. at 353; Mem. at 18-20. A plaintiff need not assert a direct cause of action for fraud on the DEA for *Buckman* preemption to apply. *See*, *e.g.*, *Marsh v. Genentech*, 693 F.3d 546, 554 (6th Cir. 2012) (applying *Buckman* not only to a direct claim of fraud on a federal agency but also to a "threshold" immunity issue necessary to the underlying claim). Nor does it matter that Plaintiffs might *also* need to prove a violation of a state-law duty, *in addition to* a fraud on the DEA. *See* Opp'n at 6-7. The *Buckman* test instead focuses on whether a plaintiff's attempt to demonstrate a particular fact "critical" to their case "would exert an extraneous pull on the scheme established by Congress." *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 948 (6th Cir. 2018) (quoting *Buckman*, 531 U.S. at 353). Simply put, "state tort remedies requiring proof of fraud committed against [a federal agency] are foreclosed since federal law preempts such claims." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (citation omitted).[8]

Here, Plaintiffs' state-law claims "requir[e] proof of fraud committed against" the DEA. *Id.* To reach Plaintiffs' claim of excess prescription opioid medications in the market, Plaintiffs must first demonstrate that the Manufacturing Defendants misled the DEA into increasing quotas to a level that permitted excess opioids to be sold. Attempting to do so would "exert an extraneous pull on the scheme established by Congress." *Buckman*, 531 U.S. at 353. The DEA alone is charged with striking the "somewhat delicate balance" between investigating and punishing fraud

[7] Plaintiffs focus on the fact that *Buckman* involved a consulting firm, but the Sixth Circuit has recognized no such distinction. *See, e.g.*, *Marsh v. Genentech, Inc.*, 693 F.3d 546, 550 (6th Cir. 2012) ("The plaintiffs in *Buckman* brought suit against a *medical-device manufacturer* under state law, alleging that *the manufacturer* had made fraudulent representations to the FDA . . . .") (emphasis added). The key issue is the conflict inherent in a court's review of a federal agency's determination within a precisely calibrated federal regulatory regime.

[8] This Court has already recognized as much, when it declined to dismiss claims in a parallel case on *Buckman* preemption grounds because the claims did *not* allege fraud on the DEA (as Plaintiffs allege here) and therefore were "not premised on a fraud upon the DEA, and thus do not run afoul of *Buckman* . . . ." *The Muscogee (Creek) Nation v. Purdue Pharma L.P.*, No. 1:17-md-02804, 2019 WL 2468267, at *22 (N.D. Ohio Apr. 1, 2019), *adopted by* Op. & Order, ECF No. 1203, at 2.

while carrying out its duty to ensure public access to beneficial opioid medications. *See id.* at 348; Mem. 18-19; *see also* Mem. in Supp. of Pls' Mot. for Summ. J. of Defs' Duties Under the Controlled Substances Act at 9 (Dkt. 1887-1) ("Congress left it to the DEA to determine what constitutes 'effective control against diversion' . . . ."). Permitting state-law fraud-on-the-DEA claims to proceed risks "dramatically increas[ing]" the regulatory burdens on Manufacturers and incentivizing Manufacturers "to submit a deluge of information" that the DEA "neither wants nor needs." *Buckman*, 531 U.S. at 350-52. It also risks inconsistent determinations by courts and the DEA. Plaintiffs' fraud-on-the-DEA claims "inevitably conflict" with the DEA's statutory responsibility to "police fraud consistently with [its] judgments and objectives." *See id.* at 350; *see also In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1325 (S.D. Fla. 2010) ("[I]f the Court were to find fraud-on-the-[DEA] when the [DEA] itself has not made such a finding, the Court would be intruding upon the [DEA]'s right to police itself and second-guessing what the [DEA] would have done had it received the information that was allegedly withheld from it by the defendant-company.")

Because all of Plaintiffs' state-law claims require proof that the DEA was misled into permitting excess prescription opioid medications in the market, they are preempted and must be dismissed. Similarly, Plaintiffs do not dispute that their RICO claims are precluded to the extent they rely upon fraud on the DEA, and so for all the same reasons, Plaintiffs' RICO claims should be dismissed as well.

CONCLUSION

For the foregoing reasons, the Court should grant Manufacturers' motion for summary judgment.

Dated: August 16, 2019

Respectfully submitted,

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[9] Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

LOCAL RULE 7.1(F) CERTIFICATION

I hereby certify that this case has been assigned to the "litigation track" and that this Memorandum adheres to the page limitations set forth in the Amended Order Regarding Pretrial Motions for "Track One" Trial (ECF No. 1709) and L.R. 7.1(f).

Dated: August 16, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on August 16, 2019, a copy of the foregoing Manufacturer Defendants' Reply in Support of Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded has been served on the Parties, the Court, and the Special Masters pursuant to the Directions Regarding Filing of Briefs Under Seal (ECF No. 1719).

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